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BY ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket ID: 2004S-0170 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggested Priority Topics for Research, FY 2006.

Wyeth Pharmaceuticals appreciates the opportunity to submit comments on the suggested research priorities for fiscal year 2006 under Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research-driven pharmaceutical and health care products companies with leading products in areas of women's health, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines.

Section 1013 of the MMA requires the Agency for Healthcare Research and Quality (AHRQ) to conduct research, demonstrations and evaluations to improve the quality, effectiveness, and efficiency of health care delivered under the Medicare, Medicaid, and State Children's Health Insurance (SCHIP) programs. Wyeth supports conducting research that will improve the quality of health care delivery, especially to the vulnerable populations covered by these programs. As a research-based company committed to improving health through innovative science that relies on clinical evidence, Wyeth has extensive experience in the types of activities required under Section 1013. In addition to broadly endorsing the stated goals of Section 1013, we would respectfully like to offer some technical and procedural suggestions to AHRQ in the following areas: (1) the scope of AHRQ's research and evaluations; (2) the diseases and conditions that should receive the highest priority; and (3) obtaining public input to facilitate the research and the dissemination of research findings.

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Recommendations

AHRQ should establish a broad, patient-centered research agenda that focuses on the entire health care system.

A key research objective under Section 1013 is to address “the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs).” Most health care experts acknowledge the increasingly important role of pharmaceuticals in the health care system and patient care over the last few decades. With growing frequency, prescription medicines help prevent the onset of or limit the progression of diseases and reduce or slow the growth of expenditures for the most costly types of health care interventions (e.g., hospitalization).¹ Yet, pharmaceuticals only account for about one-tenth (11%) of total U.S. health spending. By comparison, hospital care accounts for about one-third (31%) of U.S. health spending.

In light of the growing body of evidence that pharmaceuticals reduce spending on other health care treatments, Wyeth recommends that AHRQ develop a broad research agenda that focuses on the value of treatments across the entire U.S. health care system rather than silos within the system. Following this approach, AHRQ’s research agenda should examine a broad range of health care items and services used to treat a condition and not limit research strictly to pharmaceuticals. This broad perspective should also take into account the unique value provided by pharmaceuticals, such as improved quality of life and increased productivity.

Wyeth also recommends that AHRQ conduct research to identify the appropriate use of clinically-effective treatments and the optimal allocation of health care resources, including over- and underutilization of clinically-effective treatments. Moreover, AHRQ should consider incentives that may encourage or discourage the appropriate delivery of care. The appropriate use of clinically-effective treatments not only provides the best health outcomes for individual patients but also improves the financial health of the health care system. Although most discussions about appropriate use of clinically-effective treatments stress cost savings from reducing unnecessary care and overuse of services, it is important to

¹ Frank R. Lichtenberg, “Benefits and Costs of Newer Drugs: An Update,” (Cambridge, MA: National Bureau of Economic Research, June 2002). This study found that for every additional \$1 spent on new drugs, non-drug expenditures are reduced by \$8.38.



remember that outcomes research has uncovered gaps in the quality of care, including under-use of many evidence-proven treatments. For example, a June 2003 study published in the *New England Journal of Medicine* found that prescription medicines were underused in the treatment of seven out of nine conditions examined, including asthma, cerebrovascular disease, congestive heart failure, diabetes, high cholesterol, hip fracture and high blood pressure.² It is also important for AHRQ's research to examine the cause of and potential solutions to problems related to the inappropriate use of clinically-effective treatments, including issues such as cost-sharing. A recent AHRQ-sponsored study that looked at the impact of increasing co-payments on the use of prescription medicines found that drug plan enrollees may stop taking their medication instead of switching to less expensive drugs when their copayments are increased.³

AHRQ should prioritize the health conditions that warrant further research and focus on those that most impact the populations covered under Medicare, Medicaid, and SCHIP.

Wyeth recommends that AHRQ focus its research on major diseases with the highest prevalence among Medicare, Medicaid, and SCHIP populations and that place the heaviest burden on patients, society, and health care finances. In addition, Wyeth suggests that AHRQ select medical conditions for which additional research or better diffusion of information have the greatest potential to lead to improvements in the health care outcomes of covered patients and the quality, efficiency and effectiveness of the Medicare, Medicaid and SCHIP programs.

Given AHRQ's role in the Medical Expenditure Panel Survey (MEPS) and its unique position to analyze data on the most costly diseases for Medicare and Medicaid, Wyeth recommends that research priorities be based largely on the conditions identified through MEPS. A few health conditions, such as cardiovascular disease, pulmonary disease, cancer, and diabetes, account for about three-fourths of all U.S. deaths. Similarly, a few chronic conditions, such as asthma, hypertension, and diabetes, account for a major share of total health care spending. By focusing on diseases that impose the greatest burden on

² McGlynn, Elizabeth A, et al. "The Quality of Health Care Delivered to Adults in the United States." *New England Journal of Medicine* 2003;348:2635-45.

³ Huskamp, Keverka, et al. "The effect of incentive-based formularies on prescription-drug utilization and spending." *New England Journal of Medicine* 2003: 349:pp.2224-2232

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patients and the Medicare, Medicaid and SCHIP programs, AHRQ could help ensure that its research will contribute to maximizing the use of health care resources.

To further the Section 1013 goals of improving quality, effectiveness, and efficiency, Wyeth also recommends that AHRQ consider research on comprehensive prevention and disease management programs, which have the potential to improve quality for patients and deliver savings to the U.S. health care system. It is widely recognized that relatively small numbers of Medicare and Medicaid beneficiaries drive program expenditures. In 1997, half of Medicare spending was for the costliest five percent of beneficiaries. In contrast, the least costly 50 percent of beneficiaries consumed only two percent of all Medicare spending in 1997.⁴ AHRQ research into how disease management and better preventive programs could reduce Medicare and Medicaid costs and slow program spending growth would help policymakers make more informed decisions based on the real value of such programs.

AHRQ should adopt an open and transparent public process to strengthen and facilitate the forthcoming research and the dissemination of research findings.

Section 1013 requires an ongoing consultation with relevant stakeholders in identifying the highest priorities for research. We appreciate the steps taken by HHS to establish an open, public process for establishing research priorities, including calling for public comments and hosting the May 21st Open Door Forum to solicit stakeholders' input.

In that same spirit, Wyeth also recommends that HHS establish an open, public process for conducting, interpreting and communicating research. This process should:

- Allow stakeholders to provide comments and suggestions to determine how the research results are interpreted and disseminated.
- Include a vehicle for stakeholders to provide information and additional research on the existing body of knowledge.

⁴ MEDPAC Report to the Congress: Medicare Payment Policy, March 2003

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- Be an open and public process that can facilitate the dissemination of the findings from this research to the most relevant participants in the health care system including patients, clinicians, and the pharmaceutical and provider industries.

As part of this open process, it would be valuable to generate a public dialogue on the complexities of outcomes research methodologies. Given our long history and experience in conducting outcomes studies, including work on the cost-effectiveness of new pharmaceutical therapies, Wyeth and others in the pharmaceutical industry can serve as a valuable partner and resource to the agency. We look forward to working with AHRQ and HHS in this area.

Conclusion

Wyeth supports conducting research to improve the quality, effectiveness and efficiency of the Medicare, Medicaid, and SCHIP programs, as a way to better health outcomes for beneficiaries. To achieve these goals, we believe that AHRQ should develop a broad research agenda that examines the entire health care system with an emphasis on diseases and conditions that most impact the vulnerable populations covered by these programs. This agenda should also explore outcomes of preventive care and disease management programs as well as the over- and underutilization of treatments. By taking such an approach, AHRQ's research findings may be useful to policymakers as they make decisions about the allocation of health care resources. Finally, Wyeth also recommends establishing an open and public process to facilitate research and disseminate its findings.

We are pleased to have had this opportunity to provide recommendations regarding our suggested research priorities for FY06 under Section 1013 of the MMA. We look forward to working with HHS in the implementation of Section 1013. If there are any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,



Lucinda E. Long